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ILLUMINA, INC. 9885 TOWNE CENTRE DRIVE SAN DIEGO, CA 92121-1975			EXAMINER BEISNER, WILLIAM H	
			ART UNIT	PAPER NUMBER
			1744	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/606,369

Applicant(s)

STUELPNAGEL ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2006 and 09 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-40, 42-52 and 55-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-40, 42-52 and 55-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/9/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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4. Claims 37-40, 42-51, 55 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitehead et al.(US 4,879,097) in view of Kolehmainen et al.(US 4,349,510) and Tajima et al.(US 5,682,232) taken further in view of Walt et al.(US 6,327,410).

The reference of Whitehead et al. discloses a device for forming a chamber which includes a base plate (10, 11) which holds a microtiter plate (16, 17). The device includes a lid including component ports for immobilizing array components (28 or 350). The device includes sealant (21) between the base and the lid.

While the reference of Whitehead et al. discloses sealant, 21, so as to seal the chamber to prevent entry of stray light (See the abstract), the instant claims recite that the sealant provides an "airtight" seal.

The reference of Kolehmainen et al. discloses an optical analysis system which detects chemiluminescence. The reference of Kolehmainen et al. discloses that a light-tight seal can be maintained using an o-ring, 38 (See column 4, lines 6-27). The light-tight seal prevents external light from interfering with the detector.

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to employ an o-ring seal in place of seal, 21, in device of Whitehead et al. for the known and expected result of providing an alternative means recognized in the art to achieve the same result, sealing the interior of the reaction region from exterior light. Use of an o-ring as suggested by the reference of Kolehmainen et al. would inherently result in an airtight seal. Furthermore, the use of an o-ring to form the light-tight seal of Whitehead et al. would be advantageous over the seal (21) of

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Whitehead et al. because the o-ring would also provide an air-tight seal that would provide better contamination protection with respect to contaminants entering the reaction chamber.

While the combination of the references of Whitehead et al. and Kolehmainen et al. suggests the use of an o-ring-type of seal for creating a light-tight seal, the instant claims further differ by reciting that the device includes “a clamp providing increased pressure between said lid and said base plate”.

The reference of Tajima et al. discloses that when forming a light-tight seal between a base plate (9) and a lid (5) it is known in the art to employ an elastic sealing member (See column 4, lines 43-53). The reference also discloses the use of a clamping device (8) for increasing the pressure between the lid (5) and the base plate (9).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the device of the modified primary reference with a clamp device for the known and expected result of providing an art recognized means for comprising an elastic sealing member, such as an o-ring, so as to provide a light-tight seal with respect to the lid and base plate of the detection housing.

With respect to claims 37-40, the lid of the device of Whitehead et al. includes openings or ports that include second array components (28, 129, 228).

Also, claims 37-40 differ by reciting that the second array component of the lid includes arrays of bioactive agents, specifically, a substrate that includes discrete sites containing a microspheres of distinctive bioactive agents.

The reference of Whitehead et al. discloses that the disclosed supports (129) can take the form of fiber optic sensors (See column 9, lines 61-66).

The reference of Walt et al. discloses that the use of a substrate including discrete sites and a population of microspheres comprising first and second subpopulations distributed on the discrete sites wherein each subpopulation includes a distinct bioactive agent is known in the art (See column 4, line 35, to column 5, line 31).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ the fiber optic sensor devices disclosed in the reference of Walt et al. in the system of the reference of Whitehead et al. for the known and expected result of providing a means recognized in the art for contacting a fiber optic sensor with a sample for analyte detection. Advantages of using the fiber optic sensor of Walt et al. over other prior art sensors include the ease of manufacture and the ability to perform high density screening of samples. Use of the system of Whitehead et al. for contacting the fiber optic sensor with a sample of analyte would allow a plurality of samples to be simultaneously contacted with a plurality of separate fiber optic sensors while maintaining a light-tight environment. As shown in Figure 3 of Walt et al. the sample solution contained within the wells of the microplate would include a plurality of different target analytes having a fluorescent label (See elements 62a, 62b and 62c).

With respect to claims 42 and 43, the reference of Walt et al. discloses the claimed density of bioactive agents (See column 5, lines 4-23).

With respect to claims 44 and 45, while the reference of Whitehead et al. employs a 6x10 array of wells, it would have been obvious to one of ordinary skill in the art to modify the system to employ any of the standard microplate formats known in the art.

With respect to claims 46 and 47, the device includes male/female alignment means (22).

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With respect to claim 48, as shown in Figure 11, the chamber is connected to at least one fluid-handling device (350).

With respect to claims 36, 49 and 50, the reference of Walt et al. discloses the use of subpopulations and/or random array of microspheres.

With respect to claim 51, the reference of Walt et al. discloses list of possible bioactive agents (See column 7, line 55, to column 8, line 67) that includes peptides and nucleic acids.

With respect to claim 55, when using the random array of microspheres as suggested by the reference of Walt et al., the sample holding or assay location microplate would include a plurality of analytes. Furthermore, the reference of Walt et al. discloses that it is known to fluorescently label the target analytes (See column 21, lines 17-25).

With respect to claim 57, the reference of Tajima et al. also suggests the use of a clamp for maintaining the seal between the bottom and bottom components.

5. Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Whitehead et al.(US 4,879,097) in view of Kolehmainen et al.(US 4,349,510), Tajima et al.(US 5,682,232) and Walt et al.(US 6,327,410) taken further in view of Heffelfinger et al.(US 5,784,152).

The combination of the references of Whitehead et al., Kolehmainen et al. Tajima et al. and Walt et al. has been discussed above.

Claim 52 differs by reciting that the device further includes a heating device.

The reference of Heffelfinger et al. discloses that it is conventional in the art to provide a system for optically monitoring chemical reactions within a microplate with a temperature controlled incubator (102).

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In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the system of the modified primary reference with a device for controlling the temperature during the reaction for the known and expected result of ensuring that the proper temperature is maintained during the optical monitoring of the reaction. Note the temperature control device would inherently include a heating device. The temperature maintained within the device would have been merely based on the specifics of the reaction that is to be monitored within the device.

6. Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Whitehead et al.(US 4,879,097) in view of Kolehmainen et al.(US 4,349,510), Tajima et al.(US 5,682,232) and Walt et al.(US 6,327,410) taken further in view of Balch (US 6,083,763).

The combination of the references of Whitehead et al., Kolehmainen et al. Tajima et al. and Walt et al. has been discussed above.

Claim 56 differs by reciting that the second array component is not a fiber optic member.

The reference of Balch discloses that when imaging a chemical reaction, it is known in the art to employ a ccd imager without the use of fiber optic structures (See Figure 1 and related text).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ the microsphere arrays disclosed by the reference of Walt et al. with a ccd imaging device rather than fiber optic structures for the known and expected results of providing an alternative means recognized in the art for imaging the reaction wells of the detection device.

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7. Claims 39-47, 49-51 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al.(US 6,327,410) in view of Rushbrooke et al.(US 4,922,092).

The reference of Walt et al. discloses that the use of a substrate including discrete sites and a population of microspheres comprising first and second subpopulations distributed on the discrete sites wherein each subpopulation includes a distinct bioactive agent is known in the art (See column 4, line 35, to column 5, line 31).

While the reference of Walt et al. requires contacting the substrate with the discrete sites with a sample solution including a plurality of different target analytes having a fluorescent label (See Figure 3 and related text), the reference does not specifically disclose the use of a base plate or first array component for holding the sample solution and an associated lid for contacting the second array component with the first array component.

The reference of Rushbrooke et al. discloses that it is known in the art to interface a fiber optic component (See Figures 5 and 6) with a multiwell plate using a lid (148) and sealant (140,142) between the lid and plate (112).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to interface the detection arrays of the reference of Walt et al. with a plurality of sample solutions in the manner suggested by the reference of Rushbrooke et al. for the known and expected result of providing an art recognized means for interfacing an optical sensor with a sample solution.

With respect to the claimed alignment structures, if the device of the modified primary reference does not inherently include an alignment structure, it would have been obvious to one of ordinary skill in the art to provide an alignment structure for the known and expected result of

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providing a means known in the art for ensuring that the upper sensor component is properly aligned with the sample well including the sample solution.

With respect to claim 41, it would have been obvious to one of ordinary skill in the art to coat each support (129) with a different bioactive agent for the known and expected result of providing a means for simultaneously performing a plurality of different luminescent immunospecific assays.

With respect to claims 42 and 43, the reference of Walt et al. discloses the claimed density of bioactive agents (See column 5, lines 4-23).

With respect to claims 44 and 45, while the reference of Whitehead et al. employs a 6x10 array of wells, it would have been obvious to one of ordinary skill in the art to modify the system to employ any of the standard microplate formats known in the art.

With respect to claims 46 and 47, the device includes male/female alignment means (22).

With respect to claims 49 and 50, the reference of Walt et al. discloses the use of subpopulations and/or random array of microspheres.

With respect to claim 51, the reference of Walt et al. discloses list of possible bioactive agents (See column 7, line 55, to column 8, line 67) that includes peptides and nucleic acids.

With respect to claim 55, when using the random array of microspheres as suggested by the reference of Walt et al., the sample holding or assay location microplate would include a plurality of analytes. Furthermore, the reference of Walt et al. discloses that it is known to fluorescently label the target analytes (See column 21, lines 17-25).

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8. Claims 37-40, 42-51, 55 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al.(US 6,327,410) in view of Rushbrooke et al.(US 4,922,092) taken further in view of Paffhausen et al.(US 6,191,852).

The combination of the references of Walt et al. and Rushbrooke et al. has been discussed above.

The above claims differ by reciting that the base plate includes a cavity and/or the device includes an alignment structure.

The reference of Paffhausen et al. discloses that when interfacing a fiber optic sensors with a microwell plate, it is know in the art to provide a base plate with a cavity for supporting the microwell plate (See Figure 6).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to interface the fiber optic elements and microwell plate of the modified primary reference using the alignment system of the reference of Paffhausen et al. for the known and expected result of providing an alternative means recognized in the art for interfacing and aligning a plurality of fiber optic sensors with a plurality of wells.

With respect to claim 57, the device includes a clamp means (29).

With respect to claims 34 and 48, the reference also discloses the use of fluid handling device (35).

9. Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al.(US 6,327,410) in view of Rushbrooke et al.(US 4,922,092) taken further in view of Heffelfinger et al.(US 5,784,152).

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The combination of the references of Walt et al. and Rushbrooke et al. has been discussed above.

Claim 52 differs by reciting that the device further includes a heating device.

The reference of Heffelfinger et al. discloses that it is conventional in the art to provide a system for optically monitoring chemical reactions within a microplate with a temperature controlled incubator (102).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the system of the modified primary reference with a device for controlling the temperature during the reaction for the known and expected result of ensuring that the proper temperature is maintained during the optical monitoring of the reaction. Note the temperature control device would inherently include a heating device. The temperature maintained within the device would have been merely based on the specifics of the reaction that is to be monitored within the device.

10. Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al.(US 6,327,410) in view of Rushbrooke et al.(US 4,922,092) taken further in view of Balch (US 6,083,763).

The combination of the references of Walt et al. and Rushbrooke et al. has been discussed above.

Claim 56 differs by reciting that the second array component is not a fiber optic member.

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The reference of Balch discloses that when imaging a chemical reaction, it is known in the art to employ a ccd imager without the use of fiber optic structures (See Figure 1 and related text).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ the microsphere arrays disclosed by the reference of Walt et al. with a ccd imaging device rather than fiber optic structures for the known and expected results of providing an alternative means recognized in the art for imaging the reaction wells of the detection device.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 39-47, 49-51 and 55 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 6,429,027 in view of Rushbrooke et al.(US 4,922,092).

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Claims 1-30 of U.S. Patent No. 6,429,027 encompass a device that includes a substrate including discrete sites and a population of microspheres comprising first and second subpopulations distributed on the discrete sites wherein each subpopulation includes a distinct bioactive agent.

While the patented claims require contact between the first and second components, the claims do not specifically disclose the use of a base plate or first array component for holding the sample solution and an associated lid for contacting the second array component with the first array component.

The reference of Rushbrooke et al. discloses that it is known in the art to interface a fiber optic component (See Figures 5 and 6) with a multiwell plate using a lid (148) and sealant (140,142) between the lid and plate (112).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to interface the detection arrays of the patented claims with a plurality of sample solutions in the manner suggested by the reference of Rushbrooke et al. for the known and expected result of providing an art recognized means for interfacing an optical sensor with a sample solution.

With respect to the claimed alignment structures, if the device of the modified primary reference does not inherently include an alignment structure, it would have been obvious to one of ordinary skill in the art to provide an alignment structure for the known and expected result of providing a means known in the art for ensuring that the upper sensor component is properly aligned with the sample well including the sample solution.

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13. Claims 37-40, 42-51, 55 and 57 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 6,429,027 in view of Rushbrooke et al.(US 4,922,092) taken further in view of Paffhausen et al.(US 6,191,852).

The combination of the patented claims and Rushbrooke et al. has been discussed above.

The above claims differ by reciting that the base plate includes a cavity and/or the device includes an alignment structure.

The reference of Paffhausen et al. discloses that when interfacing a fiber optic sensors with a microwell plate, it is know in the art to provide a base plate with a cavity for supporting the microwell plate (See Figure 6).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to interface the fiber optic elements and microwell plate of the modified primary reference using the alignment system of the reference of Paffhausen et al. for the known and expected result of providing an alternative means recognized in the art for interfacing and aligning a plurality of fiber optic sensors with a plurality of wells.

With respect to claim 57, the device includes a clamp means (29).

With respect to claims 34 and 48, the reference also discloses the use of fluid handling device (35).

14. Claim 52 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 6,429,027 in view of Rushbrooke et al.(US 4,922,092) taken further in view of Heffelfinger et al.(US 5,784,152).

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The combination of the patented claims and Rushbrooke et al. has been discussed above.

Claim 52 differs by reciting that the device further includes a heating device.

The reference of Heffelfinger et al. discloses that it is conventional in the art to provide a system for optically monitoring chemical reactions within a microplate with a temperature controlled incubator (102).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the system of the modified primary reference with a device for controlling the temperature during the reaction for the known and expected result of ensuring that the proper temperature is maintained during the optical monitoring of the reaction. Note the temperature control device would inherently include a heating device. The temperature maintained within the device would have been merely based on the specifics of the reaction that is to be monitored within the device.

15. Claim 56 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 6,429,027 in view of Rushbrooke et al. (US 4,922,092) taken further in view of Balch (US 6,083,763).

The combination of the patented claims and Rushbrooke et al. has been discussed above.

Claim 56 differs by reciting that the second array component is not a fiber optic member.

The reference of Balch discloses that when imaging a chemical reaction, it is known in the art to employ a ccd imager without the use of fiber optic structures (See Figure 1 and related text).

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In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ the microsphere arrays disclosed by the reference of Walt et al. with a ccd imaging device rather than fiber optic structures for the known and expected results of providing an alternative means recognized in the art for imaging the reaction wells of the detection device.

Response to Arguments

16. With respect to the rejection of Claims 29-51, 55 and 57 under 35 U.S.C. 103(a) as being unpatentable over Whitehead et al.(US 4,879,097) in view of Kolehmainen et al.(US 4,349,510) and Tajima et al.(US 5,682,232) taken further in view of Walt et al.(US 6,327,410), Applicants argue that the rejection is improper for the following reasons:

i) There would not have been any motivation to modify the device to include sample solutions having fluorescently labeled analytes in the assay locations (See page 7 of the response filed 12/20/06).

In response, the Examiner again points out that the reference of Whitehead et al. itself provides the motivation for the modification. The reference discusses alternative configurations of the device that includes coated supports dipped into the reaction vessels containing luminogenic reagent (See column 9, lines 23-30) and the use of fiber optic sensors and the use of luminescence and other analytical techniques simultaneously (See column 9, lines 61-66). As a result, the Examiner is of the position that one of ordinary skill in the art would have clearly recognize the obviousness of using devices such as those of Walt et al. in place of and/or in addition to the detection employed in the system of Whitehead et al.

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It also appears that Applicants are arguing that the only difference between the structure of the claimed device and that of the prior art is the presence of the sample solution. It is noted that claiming “material worked on” in an apparatus-type claim is not sufficient to define the structure of the device over the prior art when the “material worked on” is the only difference (See MPEP 2115).

ii) Changing the device of Whitehead et al. from one that detects luminescence to one that can detect fluorescence would make the device more complex. Applicants stress that the reference of Whitehead et al. is merely concerned with the detection of luminescence using simple photographic methods (See pages 7-8 of the response filed 12/20/06).

In response, the Examiner again points out that the reference of Whitehead et al. itself provides the motivation for the modification. The reference discusses alternative configurations of the device that includes coated supports dipped into the reaction vessels containing luminogenic reagent (See column 9, lines 23-30) and the use of fiber optic sensors and the use of luminescence and other analytical techniques simultaneously (See column 9, lines 61-66). As a result, the Examiner is of the position that one of ordinary skill in the art would have clearly recognize the obviousness of using devices such as those of Walt et al. in place of and/or in addition to the detection employed in the system of Whitehead et al. The Examiner notes that Applicants’ comments are silent with respect to this specific disclosure within the Whitehead et al. reference.

iii) Applicants disagree with the Examiner’s previous comments that “the reference of Walt et al. does not require that the sample solution be removed from the array since the array of

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Walt et al. is capable of detecting a binding between an analyte in solution with the detection array. Any analyte in the solution that does not bind to the array is not detected”.

In response, the Examiner maintains that the structure of Walt et al. is capable of detecting only bound analyte in view of the disclosure that “the change in optical signal occurs as a result of the binding of a target analyte” (See column 22, line 66, to column 23, line 7). Any unbound labeled analyte would not provide a change in optical signal and thus would not interfere with the detection of bound analyte.

17. With respect to the rejection of claim 52 under 35 USC 103 over the combination of the references of Whitehead et al, Kolehmainen et al., Tajima et al., Walt et al. and Heffelfinger et al., Applicants argue (See pages 9-10 of the response filed 12/20/06) that the rejection is improper because the reference of Heffelfinger et al. does not cure the deficiencies associated with the combination of the references of Whitehead et al., Kolehmainen et al. and Tajima et al. and discussed at length previously.

In response, the reference of Heffelfinger et al. was not relied upon to provide motivation for replacing a labyrinth seal with an o-ring. The combination of the references of Whitehead et al., Kolehmainen et al. and Tajima et al. address this claim limitation. The reference of Heffelfinger et al. was relied upon as an additional teaching that addresses the obviousness of employing a heating device.

18. With respect to the rejection of claim 56 under 35 USC 103 over the combination of the references of Whitehead et al, Kolehmainen et al., Tajima et al., Walt et al. and Balch,

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Applicants argue (See pages 10 of the response filed 12/20/06) that the rejection is improper because the reference of Balch does not cure the deficiencies associated with the combination of the references of Whitehead et al., Kolehmainen et al. and Tajima et al. and discussed at length previously. Applicants stress that the Examiner previously states that it would have been obvious to employ a fiber optic array and than also states that it would have been obvious to not use a fiber optic array. Applicants stress that the Examiner does not have motivation for the combination suggested by the Examiner.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, while the references of Whitehead et al. and Walt et al. suggest the use of a fiber optic array, the reference of Balch suggests that a fiber optic array can be replaced with a CCD camera.

19. With respect to the rejection of Claims 39-47, 49-51 and 55 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 6,429,027 in view of Rushbrooke et al.(US 4,922,092), Applicants argue (See page 11 of the response filed 12/20/06) that the rejection is improper because the rejection lacks the require motivation.

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In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one of ordinary skill in the art when presented with the disclosures of the references of Walt et al. and Rushbrooke et al. would have clearly recognized the benefits of contacting the fiber optic devices of Walt et al. with a plurality of samples using a device as disclosed by the reference of Rushbrooke et al. While the reference of Walt et al. is concerned with contacting the fiber optic sensors with a sample solution, the reference is silent as to how the two are contacted other than by dipping. Upon review of the disclosure of Rushbrooke et al. one of ordinary skill in the art would have found it obvious to contact sample solutions as disclosed in Rushbrooke et al. so as to allow a plurality of samples to be simultaneously contacted without contamination between samples.

20. With respect to the rejection of Claims 29-51, 55 and 57 under 35 U.S.C. 103(a) as being unpatentable over Walt et al.(US 6,327,410) in view of Rushbrooke et al.(US 4,922,092) taken further in view of Paffhausen et al.(US 6,191,852), Applicants maintain that the rejection is improper for the same reasons as set forth above with respect to the combination of the references of Walt et al. and Rushbrooke et al. (See pages 11-12 of the response filed 12/20/06).

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In response, the Examiner maintains that the rejection is proper for the same reasons as set forth above with respect to the combination of the references of Walt et al. and Rushbrooke et al..

21. With respect to the rejection of Claim 52 under 35 U.S.C. 103(a) as being unpatentable over Walt et al.(US 6,327,410) in view of Rushbrooke et al.(US 4,922,092) taken further in view of Heffelfinger et al.(US 5,784,152), Applicants maintain that the rejection is improper for the same reasons as set forth above with respect to the combination of the references of Walt et al. and Rushbrooke et al. (See page 12 of the response filed 12/20/06).

In response, the Examiner maintains that the rejection is proper for the same reasons as set forth above with respect to the combination of the references of Walt et al. and Rushbrooke et al..

22. With respect to the rejection of Claim 56 under 35 U.S.C. 103(a) as being unpatentable over Walt et al.(US 6,327,410) in view of Rushbrooke et al.(US 4,922,092) taken further in view of Balch (US 6,083,763), Applicants maintain that the rejection is improper for the same reasons as set forth above with respect to the combination of the references of Walt et al. and Rushbrooke et al. (See pages 12-13 of the response filed 12/20/06).

In response, the Examiner maintains that the rejection is proper for the same reasons as set forth above with respect to the combination of the references of Walt et al. and Rushbrooke et al..

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23. With respect to the obviousness-type double patenting rejections of record, Applicants argue that the rejections are not proper for the same reasons as set forth with respect to the combination of the references of Walt et al. and Rushbrooke et al. (See pages 13-15 of the response filed 12/20/06).

In response, the Examiner maintains that the rejection is proper for the same reasons as set forth above with respect to the combination of the references of Walt et al. and Rushbrooke et al..

Conclusion

24. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


William H. Beisner
Primary Examiner
Art Unit 1744

WHB